

# In the United States Court of Federal Claims

No. 15-1417V

(Filed: December 10, 2020)\*

\*Opinion originally issued under seal on November 10, 2020

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MICHAEL BAILEY JR., <i>on behalf</i>	)	
<i>of the Estate of Michael Bailey, Sr.,</i>	)	
	)	
Petitioner,	)	
	)	
v.	)	Vaccine Act; Initial Injury; Off-Table;
	)	42 U.S.C. 300aa-10, <i>et seq.</i>
<i>Secretary of Health and Human</i>	)	
<i>Services,</i>	)	
	)	
Respondent.	)	
	)	

*Braden Andrew Blumenstiel*, The Law Office of Dupont & Blumenstiel, Dublin, Ohio, for petitioner.

*Colleen Clemons Hartley*, Torts Branch, Civil Division, United States Department of Justice, Washington DC, with whom were *Joseph H. Hunt*, Assistant Attorney General, *C. Salvatore D'Alessio*, Acting Director, and *Alexis B. Babcock*, Assistant Director, for respondent.

## OPINION<sup>1</sup>

**FIRESTONE**, *Senior Judge*.

Pending before the Court is Petitioner Michael Bailey Jr.'s Motion for Review of Special Master Oler's (the "Special Master") April 24, 2020 Decision (the "April 24,

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<sup>1</sup> Pursuant to Rule 18(b) of Appendix B of the Rules of the United States Court of Federal Claims ("RCFC, App. B"), this Opinion was initially filed under seal on November 10, 2020. The parties had more than fourteen days from the date of filing of this Opinion to propose redactions of any of the information herein. Neither party submitted any redactions.

2020 Decision”) denying a claim for compensation pursuant to the National Vaccine Injury Compensation Program, codified at 42 U.S.C. 300aa-10, *et seq.* (the “Vaccine Act”), which he is maintaining on behalf of his late father, Michael Bailey, Sr. (“Mr. Bailey”).<sup>2</sup> The court heard oral argument on this motion on November 3, 2020. For the reasons stated below, the Court denies Petitioner’s motion and sustains the decision of the Special Master.

## **I. BACKGROUND**

On November 23, 2015, Mr. Bailey filed a petition seeking compensation under the Vaccine Act based on his claim that a dosage of the flu vaccine Fluarix administered on December 12, 2012 caused him to suffer “heart palpitations, dizziness, and headaches” within days, and loss of control of his hands, arms and legs in the months and years that followed, ultimately leaving Mr. Bailey “totally disabled and reliant on others for total daily care.” Pet. at 1, 3, ECF No. 1 (the “Petition”). While Mr. Bailey acknowledged in his petition that his doctors attributed these symptoms to amyotrophic lateral sclerosis (“ALS”), he based his compensation claim on his contention that “he has every symptom associated with Guillain-Barre Syndrome [(“GBS”)], which has been recognized as an adverse reaction to the Fluarix Vaccination.” *Id.* at 3-4.

### **A. Procedural History**

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<sup>2</sup> As noted below, Mr. Bailey died on July 28, 2017, nearly two years after filing the petition currently before this court. Following his death, his son Michael Bailey, Jr., elected to continue the prosecution of the estate’s claim. As did the Special Master in the April 24, 2020 Decision, the court refers to Mr. Michael Bailey Sr. as “Mr. Bailey” and Mr. Michael Bailey, Jr. as “Petitioner.” *See* April 24, 2020 Decision at 1, n.2.

After Mr. Bailey had filed his medical records, the Secretary for Health and Human Services (the “Secretary” or the “Respondent”) on April 5, 2016 filed a Rule 4(c)<sup>3</sup> report, in which the Secretary argued that the Petition should be dismissed on the ground that Mr. Bailey’s medical records indicated that he was suffering from ALS and he had failed to establish that he suffered from GBS. In the alternative the Secretary argued that Mr. Bailey had failed to establish that his flu vaccination had caused his injury. Resp’t Report at 10-11, ECF No. 24. Specifically, the Secretary argued that Mr. Bailey “ha[d] not established that any of the symptoms he reported . . . are symptoms of GBS” and that “neither [his] medical records, his clinical presentation, nor his test results support a diagnosis of GBS.” *Id.* Upon review of the Rule 4(c) Report, the Special Master ordered Mr. Bailey to file an expert report by June 6, 2016. Scheduling Order dated Apr. 6, 2020, ECF No. 25.

On June 28, 2016, Mr. Bailey filed an expert report authored by Dr. Philip DeMio, a medical doctor, who opined that Mr. Bailey suffered from GBS, not ALS, based on his examination of Mr. Bailey, review of Mr. Bailey’s medical records, and review of statements authored by Mr. Bailey and his family. Expert Report of Dr. Philip DeMio at 1-3, ECF No. 31 (the “DeMio Report”). Mr. Bailey did not include Dr. DeMio’s curriculum vitae with his expert report, but, in the report, Dr. DeMio describes himself as “a medical doctor who has cared for patients since 1984” with a practice that “gives

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<sup>3</sup> Rule 4(c) of the Vaccine Rules of the United States Court of Federal Claims requires the Secretary to file a report that sets forth “a full and complete statement of its position as to why an award should or should not be granted” after a petitioner seeking compensation under the Vaccine Act “has satisfied all required documentary submissions.” Rules of the U.S. Court of Federal Claims, App. B, Vaccine Rule 4(c).

detailed ongoing care, including diagnosis and treatment, to patients with chronic sustained illnesses including those of neurologic and immunologic disorders.” *Id.* at 1. Dr. DeMio is not a neurologist. *Id.*

On September 12, 2016, Mr. Bailey filed a transcript of the August 24, 2016 deposition of Dr. Erik Pioro, one of Mr. Bailey’s treating physicians and the director of the Cleveland Clinic’s ALS clinic, to support his claim. Dep. of Erik Pioro, M.D., ECF No. 38-1 (the “Pioro Dep.”). In his deposition, Dr. Pioro testified regarding his professional background; the differences between GBS and ALS; and his treatment of Mr. Bailey. Dr. Pioro testified that ALS is a “motor neuron disease” that affects both the brain and spinal cord (as opposed to one or the other). *Id.* at 7:4-10. Dr. Pioro distinguished ALS from other motor neuron diseases that affect “other parts of the brain or spinal cord that are not purely motor,” offering the example of Parkinson’s disease. *Id.* at 7:11-16, 8:3-13. When asked whether GBS could be classified as another “complex neurodegenerative motor neuron disorder[],” Dr. Pioro explained in his deposition that GBS is “a condition that affects just the peripheral nervous system and just the peripheral nerves,” classifying it instead as a “neuromuscular condition” that is “really quite different from ALS.” *Id.* at 8:20-9:6, 37:17-18. Later, Dr. Pioro re-emphasized this distinction, testifying that GBS “is a peripheral nervous problem” whereas ALS is “a condition that primarily is in the central nervous system” with “some peripheral components.” *Id.* at 38:3-8.

With respect to his ALS diagnosis of Mr. Bailey, Dr. Pioro testified that there is “no single definitive test for ALS,” and that ALS is “diagnosed by a combination of the

symptoms . . . [and] the signs, what we find on the clinical examination as well as these ancillary tests.” *Id.* at 22:8, 23:3-8. Dr. Piro testified that because ALS is difficult to diagnose and because of the severity of the diagnosis, “it’s extremely important that we’re sure that it is ALS and nothing else.” *Id.* at 22:2-7. Dr. Piro also testified that certain clinical tests can distinguish ALS and GBS patients, despite their symptoms being similar, as “[t]he spinal fluid is going to be abnormal for [GBS]” and “[t]he EMG is going to be different in a totally different way in [GBS] than it is in ALS.” *Id.* at 51:15-52:5. Dr. Piro also testified that he could not state whether Mr. Bailey’s symptoms began before or after his December 12, 2012 flu vaccine as Dr. Piro began seeing him on August 29, 2013, several months later. *Id.* at 13:7-11. Dr. Piro did not dispute that Mr. Bailey and his family had reported that “they had no evidence prior to the vaccine of [Mr. Bailey] weakening in any fashion,” but noted that it is difficult to predict how long a patient may have had ALS before symptoms developed. *Id.* at 12:9-19, 14:20-25. Dr. Piro acknowledged that certain of Mr. Bailey’s symptoms – lack of bladder function, sexual function, headaches, heart palpitations, and dizziness – are not typical symptoms of ALS and that “other conditions can mimic it,” making ALS difficult to diagnose. *Id.* at 16:9-24, 17:17-20, 20:16-20, 21:24-25.

Counsel for the Secretary reviewed notes of the Cleveland Clinic’s treatment of Mr. Bailey for ALS and provided Dr. Piro the opportunity to explain how Mr. Bailey’s symptoms and test results supported an ALS diagnosis. *Id.* at 57:20-66:8. When asked, Dr. Piro explained that he could not say whether Mr. Bailey’s flu vaccine caused or aggravated Mr. Bailey’s ALS. *Id.* at 54:15-55:5, 66:10-16.

On February 17, 2017, the Secretary filed his expert report authored by Dr. Vinay Chaudhry, along with supporting medical literature. Expert Report of Dr. Vinay Chaudhry, ECF No. 53-1 (the “Chaudhry Report”). As discussed in detail below, Dr. Chaudhry confirmed the ALS diagnosis of Mr. Bailey’s treating physicians.

Petitioner requested the opportunity to obtain a rebuttal expert opinion to address Dr. Chaudhry’s report. On January 29, 2018, nearly a year after this request, Petitioner filed a report authored by Dr. James Lyons-Weiler, who holds his Ph.D. in ecology, evolution, and conservation biology. Expert Report of James Lyons-Weiler dated Jan. 28, 2018, ECF No. 91 (the “First Lyons-Weiler Report”). Although not a medical doctor, Dr. Lyons-Weiler prepared a table of symptoms typical of GBS and opined that Mr. Bailey’s symptoms were “consistent with both the diagnosis of GBS and, to a lesser extent, the diagnosis of ALS.” *Id.* at 3.

After reviewing all expert reports, on June 28, 2018, the Special Master held a Rule 5 status conference.<sup>4</sup> At the conference, the Special Master stated her tentative opinion that Mr. Bailey had ALS and not GBS, which she based on the fact that no treating physician had diagnosed Mr. Bailey with GBS (or had even raised it as a differential diagnosis). Rule 5 Order dated July 18, 2018 at 2, ECF No. 102. Petitioner requested an opportunity to address the Special Master’s concern.

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<sup>4</sup> Rule 5 of the Vaccine Rules of the United States Court of Federal Claims requires the special master to hold a status conference within 30 days after the Secretary files its report called for under Rule 4(c) (described above) in order to afford the parties an opportunity to address each other’s positions, review the materials submitted and evaluate the parties’ respective positions, and present tentative findings and conclusions. Rules of the U.S. Court of Federal Claims, App. B, Vaccine Rule 5.

On November 16, 2018, Petitioner submitted two supplemental expert reports authored by Dr. Lyons-Weiler. In his first supplemental report, Dr. Lyons-Weiler walked back his conclusion that Mr. Bailey's symptoms were consistent with both GBS and ALS, stating instead that Mr. Bailey's symptoms "cannot support ALS" and that it was his "medical opinion" that Mr. Bailey's first expert, Dr. DeMio, had properly concluded that Mr. Bailey suffered from GBS. Expert Report of Dr. James Lyons-Weiler dated Nov. 14, 2018, ECF No. 108 (the "Second Lyons-Weiler Report"). In his second supplemental report, Dr. Lyons-Weiler also provided a list of medical studies that he claimed demonstrated that flu vaccines can cause chronic inflammatory demyelinating polyneuropathy ("CIDP"), which, in his opinion, is similar enough to GBS and ALS to evidence that the flu vaccine can cause those conditions. Expert Report of Dr. James Lyons-Weiler dated Nov. 14, 2018, ECF No. 109 (the "Third Lyons-Weiler Report").

On December 17, 2018, the Special Master held another status conference. At that conference, the Special Master informed Petitioner that he had not yet provided evidence that supported his contention he was suffering from GBS. *See* Order dated Dec. 18, 2018 at 1, ECF No. 112. Petitioner responded that he was searching for expert medical opinions to support his cases. *Id.* Although the Special Master gave him over a year to do so, Petitioner did not submit any additional expert reports from medical doctors to support his Petition.

On December 18, 2018, the Special Master set a briefing schedule for the Secretary's requested motion to dismiss. *Id.* at 1-2. On February 28, 2019, the Special Master ordered that the Secretary style his motion as a motion for a ruling on the record

instead. On April 12, 2019, the Secretary filed his motion, arguing that Petitioner was not entitled to compensation under the Vaccine Act because: (1) Petitioner failed to show Mr. Bailey suffered from GBS; and (2) Petitioner failed to show that the flu vaccine caused his injury. Mot. for Ruling on the Record, ECF No. 115. On November 5, 2019, the Special Master held another status conference and ordered Petitioner to file a responsive brief by December 16, 2019 or his opportunity to respond would be considered waived. Order dated Nov. 5, 2019, ECF No. 124. At the conference, Petitioner represented that he had “retained” a neurologist to support his GBS diagnosis, and planned to file his responsive brief after conferring with him. *Id.* at 1. On December 16, 2019, Petitioner filed his responsive brief, but did not include any new expert evidence to support his claim that Mr. Bailey suffered from GBS. Opp’n to Mot. for Ruling on the Record, ECF No. 125 (“Pet’r’s Opp.”).

On December 27, 2019, the Special Master held another status conference during which Petitioner confirmed that he was alleging only that Mr. Bailey had GBS and that the flu vaccine caused Mr. Bailey’s GBS. Mr. Bailey expressly confirmed to the Special Master that he was not asserting that the flu vaccine had caused Mr. Bailey to develop ALS or that Mr. Bailey’s ALS was “significantly aggravated” by the flu vaccine. Order dated Dec. 27, 2019 at 1, ECF No. 126.

## **B. The April 24, 2020 Decision**

On April 24, 2020, the Special Master issued her decision denying Petitioner’s request for compensation under the Vaccine Act as the record evidence “best supported” the conclusion that Mr. Bailey suffered from ALS, not GBS. April 24, 2020 Decision at



17. The Special Master based her conclusion on a comprehensive overview of Mr. Bailey's treatment history and each of the proffered expert opinions, which the court will summarize below.

### **1. Mr. Bailey's Treatment History**

On October 30, 2012, over a month before receiving a flu vaccine, Mr. Bailey sought treatment from his orthopedist, Dr. Matthew Kay, for numbness, tingling, and loss of grip strength in his right hand. April 24, 2020 Decision at 2. At that time, Mr. Bailey reported that his symptoms "had been present for years, but had been slowly worsening over the last several months." *Id.* Dr. Kay diagnosed Mr. Bailey with right carpal tunnel syndrome, and performed a right carpal tunnel release on November 12, 2012. *Id.*

On December 12, 2012, Mr. Bailey received a flu vaccine. *Id.* at 2. Less than a month later, on January 8, 2013, Mr. Bailey visited the emergency room at the Robinson Memorial Hospital for treatment of lacerations caused by him tripping and falling. *Id.* At that time, Mr. Bailey denied experiencing headache, dizziness, and/or neck pain, and did not report feeling any numbness or tingling in his extremities. *Id.* On April 16, 2013, Mr. Bailey returned to the emergency room at the Robinson Memorial Hospital for treatment of "stroke-like symptoms," including weakness in his right upper extremity, slurred speech, right facial drooping, and balance issues. *Id.* Mr. Bailey stated that these symptoms began in January 2013. *Id.* The physician who treated Mr. Bailey that day recommended that he see his primary care provider for follow up. *Id.* at 2-3.

On April 29, 2013, Mr. Bailey visited his primary care provider, William Raux, D.O. *Id.* at 3. At that appointment, Mr. Bailey complained of weakness in his

extremities and slow speech. *Id.* Dr. Raux ordered testing and referred Mr. Bailey to a neurologist, Dr. Hugh Miller. *Id.* On May 15, 2013, Dr. Miller diagnosed Mr. Bailey with ALS based on results of a nerve conduction study (“NCS”) that was “suspicious” for early motor neuron disease, an EMG, and a physical examination. *Id.* Dr. Miller referred Mr. Bailey to the Cleveland Clinic for a second opinion. *Id.*

On August 29, 2013, Mr. Bailey visited the Cleveland Clinic to seek a second opinion of Dr. Miller’s ALS diagnosis. *Id.* Dr. Melanie Taylor examined him and concluded that her findings were consistent with a probable motor neuron disease like ALS. *Id.* Dr. Pioro, described above, agreed with Dr. Taylor’s assessment and, along with Dr. Taylor, recommended Mr. Bailey for further evaluation to rule out other possible diagnoses. *Id.* On September 23, 2013, Mr. Bailey returned to the Cleveland Clinic for an appointment with Dr. Taylor. *Id.* at 3-4. Based on additional testing, Dr. Taylor confirmed her diagnosis of “right upper extremity onset ALS” and set out treatment plan, which included both physical therapy and Riluzole, a prescription medication administered to treat the symptoms of ALS. *Id.* Dr. Pioro agreed with Dr. Taylor’s diagnosis and her treatment plan. *Id.* at 4. In line with the recommendations of Drs. Taylor and Pioro, Mr. Bailey attended physical therapy until January 2014, when he could no longer continue in light of his worsening symptoms. *Id.*

By March 2014, Mr. Bailey required use of a power wheelchair for movement, positioning, and pressure relief. *Id.* On July 23, 2014, Mr. Bailey returned to the Cleveland Clinic and presented with trouble swallowing, no upper extremity function, and breathing problems. *Id.* On December 17, 2014, Roswell Dorsett, D.O. examined

Mr. Bailey and observed that his ALS had progressed to a quadriparesis. *Id.* On July 28, 2017, nearly four years after his initial diagnosis, Mr. Bailey died. *Id.*

## **2. Expert Reports**

As stated above, Petitioner presented four reports from two experts – the report of Dr. DeMio, a medical doctor, and the reports of Dr. Lyons-Weiler, a biologist who holds a Ph.D. in ecology, evolution, and conservation biology. The Secretary presented one expert – Dr. Vinay Chaudhry, a neurologist and professor at Johns Hopkins University– in response. The court briefly summarizes each below.

As noted above, Dr. DeMio is a medical doctor – though not a neurologist – who examined Mr. Bailey to prepare his expert report. In his report, Dr. DeMio observed that Mr. Bailey “has a severe advance neuromuscular degeneration” and states that its presentation “is quite consistent with Guillain-Barre’ [sic] Syndrome,” which was “caused by his one & only influenza vaccine.” DeMio Report at 2. Dr. DeMio does not reference how or why Mr. Bailey’s case is consistent with a GBS diagnosis (or, alternatively why it is not consistent with an ALS diagnosis), instead resting on the timing of Mr. Bailey’s symptoms, the connection between the flu vaccine and GBS, and his observation that “the bulbar variant of ALS” (i.e., the type of ALS with which Mr. Bailey was diagnosed) is “rare[]” and that “many physicians would never see a case in their entire career.” *Id.* Dr. DeMio then concluded that “[m]any aspects of Mr. Bailey’s case do not fit the more usual presentation of ALS,” that one of Mr. Bailey’s neurologists “said his case is caused by the flu vaccine,” and that another of Mr. Bailey’s neurologists

“has other cases of ALS caused by the flu vaccine,” but Dr. DeMio did not expand on any of these statements or present support for them. *Id.*

Dr. Lyons-Weiler submitted three separate reports in support of Petitioner’s claim. In the first, Dr. Lyons-Weiler, who holds no medical degree, prepared a table of symptoms typical of GBS and opined that “all but one of Mr. Bailey’s symptoms support the diagnosis of GBS” based on that table. First Lyons-Weiler Report at 1. Dr. Lyons-Weiler also described a genetic test that he ordered to further assess Mr. Bailey’s diagnosis. *Id.* While Dr. Lyons-Weiler considered the report received “to fall far short of [his] professional expectations in terms of a full report,” he admitted that the limited report received “seem[ed] to favor an ALS diagnosis for Mr. Bailey.” *Id.* at 2. Indeed, Dr. Lyons-Weiler concluded that Mr. Bailey’s symptoms were “consistent with both the diagnosis of GBS and, to a lesser extent, the diagnosis of ALS.” *Id.* at 4. In his second report, Dr. Lyons-Weiler retracted his view that Mr. Bailey could be diagnosed with either GBS or ALS, stating instead that Mr. Bailey’s symptoms “cannot support ALS” and that it was his “medical opinion” that Dr. DeMio’s conclusion that Mr. Bailey suffered from GBS was “medically correct” and that Dr. Pioro’s conclusion that Mr. Bailey suffered from ALS was “medically incorrect.” Second Lyons-Weiler Report at 1, 6. In his third report, as noted above, Dr. Lyons-Weiler provided a list of medical studies that allegedly demonstrate that flu vaccines can cause chronic inflammatory demyelinating polyneuropathy (“CIDP”), which is similar enough to GBS and ALS to evidence that the flu vaccine can cause these ailments. *See generally* Third Lyons-Weiler Report.

The Secretary's expert, Dr. Chaudhry, is a neurologist who serves as the co-director of the EMG Laboratory at Johns Hopkins Hospital and as a professor of neurology at the Johns Hopkins University School of Medicine. During his career, Dr. Chaudhry has published more than 200 articles, book chapters, and related publications relevant to his field, and has received multiple grants related to the study of ALS and neuropathy. Based on a review of Mr. Bailey's medical records, along with Dr. DeMio's report and Dr. Piro's deposition transcript, Dr. Chaudhry concluded that Mr. Bailey's symptoms were "typical for the diagnosis of ALS." ECF No. 53-1, the "Chaudhry Report" at 4. In reaching that conclusion, Dr. Chaudhry reviewed Mr. Bailey's symptoms against the diagnostic criteria for both ALS and GBS and found that "[t]here is no evidence that Mr. Bailey suffered from [GBS]." *Id.* at 5. Dr. Chaudhry also countered the conclusions reached by Dr. DeMio, noting that Mr. Bailey's heart palpitations, diarrhea, and headache (i.e., symptoms not attributable to ALS) were not documented in a number of Mr. Bailey's medical records; that Mr. Bailey "wasn't sure when the symptoms precisely began" and that "it is possible that Mr. Bailey had beginning of symptoms of ALS even prior to his carpal tunnel surgery" in November 2012; that "nothing about [Mr. Bailey's] presentation is consistent with GBS"; that the "bulbar variant" of ALS (i.e., Mr. Bailey's presentation of ALS) is not at all rare. *Id.* at 6-7. Dr. Chaudhry also agreed with the "majority" of the testimony proffered by Dr. Piro at his deposition including Dr. Piro's conclusion that Mr. Bailey had ALS and not GBS, and Dr. Piro's distinctions between the two conditions. *Id.* at 7. Indeed, Dr. Chaudhry specifically states that "ALS and GBS are two different diseases with different

clinical, physiological, and pathogenic features and have different treatment and prognosis.” *Id.*

### **3. The Special Master’s Decision**

The Special Master’s April 24, 2020 decision denying Petitioner’s request for compensation under the Vaccine Act included a thorough review of the above-described record evidence. Based on that review, the Special Master held that the evidence supported the conclusion that Mr. Bailey suffered from ALS, not GBS. In reaching that decision, the Special Master stated that neither of Petitioner’s experts were “qualified to opine o[n] the issue of diagnosis” and were “not persuasive in contending that Mr. Bailey suffered from GBS” and instead credited the diagnoses of Mr. Bailey’s treating physicians, which included three neurologists, and the Secretary’s expert, Dr. Chaudhry, another neurologist. April 24, 2020 Decision at 18-20. Having concluded that “the preponderance of the evidence establishe[d] that Mr. Bailey’s injury is ALS rather than GBS,” the Special Master explained why Petitioner had not established, by a preponderance of the evidence, that the flu vaccination caused Mr. Bailey’s ALS. *Id.* at 22. The Special Master noted that Petitioner “has confirmed that he is not asserting Mr. Bailey developed ALS from the vaccine or that his pre-existing ALS was significantly aggravated by the vaccine.” *Id.* She then denied relief. *Id.*

## **II. LEGAL STANDARDS.**

### **A. Standard of Review**

The United States Court of Federal Claims has jurisdiction to review the decision of a special master, upon a properly filed motion for review. 42 U.S.C. § 300aa-12(e)(1);

Rules of the U.S. Court of Federal Claims, Appx. B, Vaccine Rule 23. Upon such review, the Court of Federal Claims may: (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision; (B) set aside any findings of fact or conclusions of law the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law; or (C) remand the petition to the special master for further action in accordance with the court's discretion. 42 U.S.C. § 300aa-12(e)(2). Different standards of review apply to different aspects of a special master's decision: "the court reviews conclusions of law under the 'not in accordance with law' standard, findings of fact under the deferential arbitrary and capricious standard, and discretionary rulings under the abuse of discretion standard." *Stillwell v. Sec'y of Health & Human Servs.*, 118 Fed. Cl. 47, 54 (2014) (citing *Masias v. Sec'y of Health & Human Servs.*, 634 F.3d 1283, 1287-88 (Fed. Cir. 2011)). Here, it is undisputed that Petitioner's challenge centers on the Special Master's conclusion that Mr. Bailey suffered from ALS and not GBS, a finding of fact subject to review under the "arbitrary and capricious" standard.

The arbitrary and capricious standard is "well understood to be the most deferential possible." *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992). With that in mind, the court acknowledges that its role in reviewing a special master decision is not to "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses – these are all matters within the purview of the fact finder."

*Porter v. Sec’y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (quoting *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1349 (Fed Cir. 2010)) (internal quotation marks omitted); *see also Milik v. Sec’y of Health & Human Servs.*, 822 F.3d 1367, 1376 (Fed. Cir. 2016) (“The arbitrary and capricious standard is ‘difficult for an appellant to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact.’” (quoting *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed Cir. 2000))). Indeed, given the court’s limited role, “reversible error is ‘extremely difficult to demonstrate’ if the special master has ‘considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.” *Wyatt v. Sec’y of Health & Human Servs.*, 144 Fed. Cl. 531, 537 (2019), *aff’d*, 825 F. App’x 880 (Fed. Cir. 2020) (internal citations omitted); *see also Porter*, 663 F.3d at 1249 (“[A]s long as a special master’s finding of fact is based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.” (internal citation and quotation marks omitted))).

## **B. Vaccine Act Standards**

To qualify for relief under the Vaccine Act, a petitioner must show by a preponderance of the evidence “that the injury or death at issue was caused by a vaccine.” 42 U.S.C. §§ 300aa-11(c)(1), 13(a)(1). The standard used to determine whether a petitioner has satisfied this initial burden differs depending on whether the alleged vaccine and injury is listed in the Vaccine Injury Table (i.e., a “Table” injury). *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(i), -14. Where a petitioner has suffered a “Table” injury,



the vaccine is presumed to have caused the injury. *Wyatt*, 825 F. App'x at 885. But, where a petitioner has suffered an “off-Table” injury, “a petitioner must prove causation-in-fact, i.e., by showing by a preponderance of the evidence: (1) a medical theory causally connecting the vaccination to the injury; (2) a logical sequence of cause and effect demonstrating that the vaccination caused the injury; and (3) a proximate temporal relationship between the vaccine and the injury.” *Austin v. Sec’y of Health & Human Servs.*, 818 F. App'x 1005, 1007 (Fed. Cir. 2020) (quoting *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). These are referred to as the *Althen* prongs.

GBS was added to the Vaccine Injury Table as of March 21, 2017. *See Black v. Sec’y of Health & Human Servs.*, No. 16-1189, 2018 WL 4390985, at \*1 n.3 (Fed. Cl. May 31, 2018) (“The final rule amending the Table to add GBS as a Table injury for the flu vaccine was published on January 19, 2017 and took effect on March 21, 2017.”). But the revised Vaccine Injury Table only governs petitions filed on or after the effective date of the final rule. *See* 42 U.S.C. § 300aa-14(c)(4) (“Any modification . . . of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.”). As stated above, Mr. Bailey filed the Petition on November 23, 2015, more than one year before GBS was added to the Vaccine Injury Table. Accordingly, Petitioner bore the initial burden to show by a preponderance of the evidence that his alleged GBS was caused by the flu vaccine.

As referenced above, the Special Master here concluded, however, that Mr. Bailey suffered from ALS, not GBS, and that Petitioner failed to prove that his December 12, 2012 flu vaccination caused his ALS. In his Motion for Review before this court, Petitioner challenges only the Special Master's conclusion that Mr. Bailey had ALS and not GBS. Mot. for Review of Decision of Special Master, ECF No. 128 ("Pet'r's Mot. for Review"). Petitioner then argues that he satisfied his burden of demonstrating that the flu vaccine caused Mr. Bailey's GBS.<sup>5</sup> *Id.*

### III. DISCUSSION

#### A. The Special Master's Decision to Determine Mr. Bailey's Injury before Addressing Causation Was Legally Proper.

Although not challenged by Mr. Bailey, the court holds as an initial matter that the Special Master's decision to first determine whether or not Mr. Bailey suffered from GBS

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<sup>5</sup> During the November 3, 2020 oral argument, Petitioner argued for the first time that the Special Master erred in neglecting to hold an evidentiary hearing before issuing the April 24, 2020 Decision. As an initial matter, because this argument was presented for the first time at oral argument (i.e., after briefing was complete), it need not be addressed. *See Novosteel SA v. United States*, 284 F.3d 1261, 1274 (Fed. Cir. 2002). Nonetheless, the court will briefly address its merits. Under Vaccine Rule 8(d), "[a] special master's decision to hold an evidentiary hearing[] . . . is discretionary." *Kreizenbeck v. Sec'y of Health & Human Servs.*, 141 Fed. Cl. 138, 139 (2018), *aff'd*, 945 F.3d 1362 (Fed. Cir. 2020); Rules of the U.S. Court of Federal Claims, Appendix B, Vaccine Rule 8 (d) ("The special master *may* decide a case on the basis of written submissions without conducting an evidentiary hearing." (emphasis added)). The Special Master's decision not to hold a hearing was upheld in *Kreizenbeck* because the Special Master "gave [the parties] ample opportunity to support their claims with written evidence and briefs." *Kreizenbeck*, 141 Fed. Cl. at 140. In the pending matter the Special Master also provided the Petitioner with ample opportunity to support his claims. She held four status conferences, accepted all of the Petitioner's expert submissions and granted Petitioner's requests for time to address her stated concerns about the strength of Petitioner's GBS claim. Petitioner took advantage of that time, using it to submit the expert reports authored by Dr. Lyons-Weiler offered in support of Petitioner's claims and to search for an additional expert report from a medical doctor (which was ultimately not filed). In view of the foregoing, the court finds that the Special Master did not abuse her discretion in electing not to hold a hearing before denying Petitioner's request for relief.

was legally proper. *See* April 24, 2020 Decision at 17. While ordinarily “the function of a special master is not to diagnose vaccine-related injuries, but instead to determine based on the record evidence as a whole and the totality of the case whether it has been shown by a preponderance of the evidence that a vaccine caused [petitioner’s] injury,” *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009) (internal brackets, quotation marks, and citations omitted), the Federal Circuit has explained that, under certain circumstances, “identifying the injury is a prerequisite to the [causation] analysis.” *Broekelschen*, 618 F.3d at 1346. Similar to the petition here, the special master in *Broekelschen* was presented with competing diagnoses: the petitioner asserted that the flu vaccine had caused him to suffer transverse myelitis (“TM”) while the Secretary contended that the petitioner suffered from anterior spinal artery syndrome. *Id.* As the underlying injury was in dispute, the Special Master first considered which of the two injuries – TM or anterior spinal artery syndrome – was best supported by the record. *Id.* The Federal Circuit upheld this approach in this “atypical” circumstance where “the injury itself is in dispute, the proposed injuries differ significantly in their pathology, and the question of causation turns on which injury [petitioner] suffered.” *Id.* The Federal Circuit has consistently upheld the standard set in *Broekelschen* when presented with similar circumstances. *See Wyatt*, 825 F. App’x at 885 (affirming that “[i]dentification of the petitioner’s injury is a prerequisite to causation analysis” where petitioner proffered two possible injuries as a basis for his claim); *Simanski v. Dep’t of Health & Human Servs.*, 601 F. App’x 982, 986 (Fed. Cir. 2015) (affirming same where the petitioner claimed that childhood vaccinations caused her child to suffer from GBS or CIPD and the

Secretary countered that her child suffered from spinal muscular atrophy with respiratory distress).

As in *Broekelschen* and its progeny, the threshold issue in this case is whether Mr. Bailey suffered from GBS, as Mr. Bailey's experts claimed, or ALS, as his treating physicians concluded and as the Secretary's expert neurologist confirmed. Petitioner does not argue that the Special Master erred in addressing Mr. Bailey's injury before addressing causation. The court thus holds, under *Broekelschen* and the cases that follow it, the Special Master properly addressed Mr. Bailey's injury first.

**B. The Special Master's Conclusion That the Record Supported Finding that Mr. Bailey Suffered from ALS and Not GBS was Not Arbitrary or Capricious.**

In his Motion for Review, Mr. Bailey contends that the Special Master's conclusion that the record supports finding that Mr. Bailey suffered from ALS and not GBS was "unreasonable, arbitrary, and an abuse of discretion." Pet'r's Mot. for Review at 8. As noted above, Petitioner's arguments center on the Special Master's decision to rely on Mr. Bailey's medical records and to credit the Secretary's expert, Dr. Chaudhry, over Petitioner's experts, Dr. DeMio and Dr. Lyons-Weiler. However, this court cannot "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses – these are all matters within the purview of the fact finder." *Austin*, 818 F. App'x at 1008 (quoting *Porter*, 663 F.3d at 1249). "[A]ssessments as to the reliability of expert testimony often turn on credibility determinations and finders of fact are entitled – indeed, expected – to make determinations as to the reliability of the evidence

presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.” *Porter*, 663 F.3d at 1250-51; *see also Broekelschen*, 618 F.3d at 1347 (“[T]he special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories,” and such credibility findings “are virtually unchallengeable on appeal”); *Chinea v. Sec’y of Health & Human Servs.*, No. 15-095, 2019 WL 1873322, at \*28 (Fed. Cl. March 15, 2019) (“Weighing the relative persuasiveness of competing expert testimony, based on a particular expert’s credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases.”). Indeed, this court is bound by “the deferential arbitrary and capricious standard of review.” *Porter*, 663 F.3d at 1251. A petitioner’s “mere disagreement” with a Special Master’s reasoned analysis will not render a decision arbitrary and capricious. *R.V. v. Sec’y of Health & Human Servs.*, 127 Fed. Cl. 136, 140 (2016). As discussed above, “as long as the special master’s conclusion is based on evidence in the record that is not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.” *Austin*, 818 F. App’x at 1008 (quoting *Milik*, 822 F.3d at 1376).

As discussed below, it is clear to the court that both the Special Master’s credibility assessments of the parties’ respective experts and her decision that the record evidence supports the conclusion that Mr. Bailey suffered from ALS and not GBS satisfy the deferential arbitrary and capricious standard.

**1. The Special Master’s Rejection of Petitioner’s Experts Was Not Arbitrary or Capricious.**

In rejecting the Petitioner’s experts’ opinions, the Special Master focused on their respective credentials, and concluded that Dr. DeMio and Dr. Lyons-Weiler were “not qualified to opine o[n] the issue of diagnosis and [were] not persuasive in contending that Mr. Bailey suffered from GBS.” April 24, 2020 Decision at 20. With respect to Dr. DeMio, the Special Master took issue with the fact that – unlike Mr. Bailey’s treating physicians and the Secretary’s expert, Dr. Chaudhry – Dr. DeMio is not a neurologist and has no specialized training in autoimmune or neurological disorders. *Id.* at 20. Indeed, Dr. DeMio himself noted that, while he diagnoses and treats “patients with chronic sustained illnesses including those of neurologic and immunologic disorders,” such patients have seen him *in tandem with* “neurologists and immunologists.” DeMio Report at 1. The Special Master also took issue with Dr. DeMio’s failure to provide any basis, “factual or medical,” to support his conclusion that Mr. Bailey suffered from GBS rather than ALS, criticizing his failure to “discuss the diagnostic criteria for GBS or compare those criteria with Mr. Bailey’s medical history before diagnosing him with GBS. April 24, 2020 Decision at 20. The Special Master appropriately evaluated Dr. DeMio’s credentials and ability to support his theory, and the Special Master’s reasoned decision not to credit Dr. DeMio’s theory is not arbitrary or capricious.

Notably, other courts have criticized (and ultimately rejected) expert reports submitted by Dr. DeMio for similar reasons, most recently in a case involving a nearly identical “after-the-fact” GBS diagnosis. *See Wyatt*, 825 F. App’x at 886 (affirming the special master’s finding that Dr. DeMio’s was “not reliable”); *see also* April 24, 2020 Decision at 20-21 (collecting cases). In affirming the Special Master in *Wyatt*, the

Federal Circuit noted that Dr. DeMio was the only doctor to diagnose the petitioner with GBS, despite none of the petitioner's treating physicians ever diagnosing her with GBS and contrary to their testimony that "they did not believe [the petitioner] ever suffered from GBS." 825 F. App'x at 886. In *Wyatt*, as here, Dr. DeMio based his diagnosis only on the portions of the petitioner's medical history he received, an examination of the petitioner that took place "several years after her vaccination," and his review of the petitioner's medical records, without conducting any of his own testing to verify his diagnosis. *Id.*

With respect to Dr. Lyons-Weiler, the court similarly finds that the Special Master's conclusion that he was not qualified to diagnosis Mr. Bailey with GBS was not arbitrary or capricious. The Special Master emphasized that she could not rely on Dr. Lyons-Weiler's GBS diagnosis of Mr. Bailey because Dr. Lyons-Weiler is not a medical doctor and his "background in biology and genetic sequences does not qualify him to opine, as an expert or otherwise, on the topic of medical diagnoses." April 24, 2020 Decision at 21. While Petitioner notes that Dr. Lyons-Weiler has "extensive experience with vaccine related issues and has published numerous peer-reviewed articles on matters concerning vaccines and adverse reactions," Pet'r's Mot. for Review at 5, n.5, that observation does not undermine the Special Master's conclusion that Dr. Lyons-Weiler, a non-medical doctor, is "inherently less qualified to opine on Mr. Bailey's correct neurologic diagnosis than a neurologist." April 24, 2020 Decision at 21.

In addition, and contrary to Petitioner's contentions, the April 24, 2020 Decision makes clear that the Special Master also considered (and rejected) the merits of

Petitioner’s experts’ reports in reaching her decision. The Special Master described the Petitioner’s experts’ opinions extensively in her decision and explicitly stated that she “considered” them, but did not find them persuasive, relevant, or useful in assessing the merits of the Petition. *See* April 24, 2020 Decision at 8-10, 20-21. The Special Master also explained – albeit implicitly – why Petitioner’s experts’ conclusions that Mr. Bailey suffered from GBS (and not ALS) were not supported by the record by crediting the Secretary’s expert’s overview of the criteria for GBS and his explanations of how Mr. Bailey failed to display those “signs or symptoms.” *Id.* at 20. Accordingly, the Special Master’s decision to reject Petitioner’s experts’ opinions was not based solely on her finding that Petitioner’s experts did not have the necessary credentials to diagnose Mr. Bailey with GBS; her decision was based on a thorough evaluation of the record evidence presented by both Petitioner and the Secretary.

**2. The Special Master’s Finding that the Record Best Supported Concluding that Mr. Bailey Suffered from ALS, not GBS, Was Not Arbitrary or Capricious.**

The Special Master’s conclusion that the record best supported a finding that Mr. Bailey suffered from ALS, not GBS, is also amply supported by record evidence and is therefore not arbitrary or capricious. It is undisputed that all of Mr. Bailey’s treating physicians – including neurologists from the Cleveland Clinic who specialize in ALS and other motor neuron diseases – confirmed the ALS diagnosis after testing him for other possible ailments. April 24, 2020 Decision at 3-4. The Federal Circuit has consistently held that medical records prepared by treating physicians are “quite probative” or “favored” when considering claims brought under the Vaccine Act. *Wyatt*, 825 F. App’x



at 886 (“As this court has previously stated, testimony from treating physicians ‘is quite probative’ since ‘treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009)); *see also Simanski*, 601 F. App’x at 988 (“[T]o the extent that the finding relied on medical records from treating physicians, we note that we have held such records can be quite probative or favored when considering issues relating to claims under the Vaccine Act.” (internal quotation omitted))).

The Special Master’s conclusion that Mr. Bailey suffered from ALS and not GBS is also supported by the Secretary’s expert, Dr. Chaudhry, a neurologist who serves as the co-director of the EMG Laboratory at Johns Hopkins Hospital and as a professor of neurology at the Johns Hopkins University School of Medicine. Chaudhry Report at 1. Dr. Chaudhry has extensive experience treating patients with ALS, evaluating over 2000 patients for neuromuscular disease (including ALS) each year. *Id.* In his report, Dr. Chaudhry confirmed Mr. Bailey’s ALS diagnosis and explained why Mr. Bailey’s symptoms do not support a diagnosis of GBS. *See* April 24, 2020 Decision at 20; Chaudhry Report at 4-5. Petitioner presents no reason for this court to believe that Dr. Chaudhry’s opinions were “wholly implausible.” *Porter*, 663 F.3d at 1249. Petitioner simply disagrees with them. As indicated above, petitioner’s mere disagreement does not provide grounds for this court to find the Special Master’s reliance on Dr. Chaudhry (and dismissal of Drs. DeMio and Lyons-Weiler) is arbitrary or capricious. *R.V.*, 127 Fed. Cl. at 140.

In view of the foregoing, the Special Master's conclusion that the record evidence "best supported" a finding that Mr. Bailey suffered from ALS and not GBS must be upheld.<sup>6</sup> *Broekelschen*, 618 F.3d at 1346.

#### IV. CONCLUSION

For the reasons stated above, the court **DENIES** Petitioner's motion for review of the Special Master's April 24, 2020 Decision; and **SUSTAINS** the decision of the Special Master. The Clerk shall enter judgment accordingly.

**IT IS SO ORDERED.**

s/Nancy B. Firestone  
NANCY B. FIRESTONE  
Senior Judge

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<sup>6</sup> The court notes that Petitioner does not challenge the Special Master's conclusion that he failed to demonstrate, by a preponderance of the evidence, that Mr. Bailey's December 12, 2012 flu vaccine caused his ALS. As such, the court has no occasion to opine on that issue.